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V8

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/786,937 01/22/97 BOUCHARD

P 235299/96001

EXAMINER

HM22/0818

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ART.UNIT

PAPER NUMBER

1654

14

DATE MAILED:

08/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/786,937

Applicant(s)

BOUCHARD et al

Examiner

C. Delacroix-M

Group Art Unit

1654

☒ Responsive to communication(s) filed on 6/3/89

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 15, 16, 18-24, 26-33 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 15, 16, 18-24, 26-33 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Claims 21, 22 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich et al.
3. Claims 15, 16, 18-24, 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diedrich et al. in view of Felberbaum et al.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received June 3, 1999.

No claims are cancelled. Claims 15, 16, 18-24 and 26-33 are currently pending.

Applicant's arguments traversing the previous grounds of rejection under 35 USC 112, paragraph 2; 35 USC 102(b); and 35 USC 103(a), set forth in paragraphs 1-6 of the office action mailed March 3, 1999 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed March 3, 1999, with the following additional comment:

Concerning the rejection of claim 18 under 35 USC 112, paragraph 2, Applicant argues that the limitations "inhibition of the action of natural LH" and "follicle development" refer to the limitations "to suppress endogenous LH" and "inducing follicle growth", respectively (see claim 15). However, said limitations in claim 18 continue to lack antecedent basis because it is not clear to what said limitations refer. Applicant should amend said limitations to read, for example, --after suppression of endogenous LH-- instead of "inhibition of the action of natural LH" and --follicle growth-- instead of "development". The same should be done in claim 19 as well. Such an amendment would establish clear antecedent basis.

Concerning the previous rejection of claims 21, 22 and 33 under 35 USC 102(b), Applicant argues that the Diedrich reference fails to teach each and every element of the claimed invention as is required by 35 USC 102. However, Applicant's single argument is not convincing. Diedrich discloses the invention substantially as claimed. See the office action mailed March 3, 1999.

With respect to the previous rejection of claims 15, 16, 18-24, 26-33 under 35 USC 103(a), Applicant argues that a conclusion regarding the FSH suppression caused by Cetorelix on injected FSH cannot be reached due to the possibly prolonged half-life. Applicant additionally argues that Diedrich does not disclose the claimed administration of .25 mg/day of Cetorelix as presented in claim 19 nor does Diedrich disclose the claimed administration of 2 to 6 mg in a single or dual dose, as presented in claim 23. Finally, Applicant argues that the Felberbaum reference is not prior art in view of the declaration received Nov. 23, 1998.

However, Applicant's arguments that a conclusion regarding the FSH suppression caused by Cetorelix on injected FSH cannot be reached due to the possibly prolonged half-life, is noted but unconvincing. The Examiner maintains that Diedrich suggests that under Cetorelix treatment suppression of FSH is less pronounced, thus reading on Applicant's claims. It is also not quite clear how said arguments distinguishes the claimed method from that of the prior art.

In addressing Applicant's argument that the claimed method administers .25 mg/day of Cetorelix, said argument is not commensurate in scope with the claims. This particular dosage amount is also not found in claim 19. With respect to the claimed administration of 2-6 mg of Cetorelix in a single or dual dose, this limitation is met by Diedrich. Please see the office action mailed March 3, 1999. Moreover, the 2-6 mg limitation is also not found in claim 23.

Finally, the declaration filed on Nov. 23, 1998 has been considered but is ineffective to overcome the Felberbaum et al. reference. The declaration is deficient in that it is not clear how said declaration serves to establish "same inventive entity" between the inventors in the instant application and the remaining author Diedrich K. in the prior art. Moreover, if the declaration is establishing same inventive entity, then paragraphs 3 and 4 of the declaration appear to contradict each other. In paragraph 3, Applicant states that they are the original inventors of the disclosure in the Felberbaum reference, yet at paragraph 4, it is stated that the co-inventors Bouchard,

Frydman, Devroey and Engel are not listed as co-authors on the Felberbaum reference because "they were not directly involved in carrying out this particular study". It is not clear to the Examiner to what "this particular study refers". If it refers to the study in the article, then the named co-inventors are actually not the inventors of the subject matter disclosed in the reference and the reference remains a publication by another.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 15, 16, 18-24, 26-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-33, 36-46 of copending Application No. 09/053,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and '152 claim methods for treating infertility disorders comprising administering, in addition to exogenous gonadotropins, an effective amount of an LHRH antagonist to suppress endogenous LH while maintaining FSH secretion at a natural level. Determination of the specific commercially known gonadotropins used to stimulate follicle growth is obvious and well within the capability of the skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful

process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 21, 22 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 34-35 of prior U.S. Patent No. 09/053,152 is a double patenting rejection.

Claim Objections

8. Claim 15 is objected to because of the following informalities: claim 15 as presented is awkwardly written, specifically, at line 5 of claim 15, before "to suppress" the word "only" should be cancelled and --effective-- should be added. Appropriate correction is required.

Conclusion

Claims 15, 16, 18-24 and 26-33 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward PhD, can be reached on (703) 308-4028. The fax phone number for this Group is (703) 308-4242.

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Applicant: BOUCHARD et al.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM *cm*

Aug. 15, 1999

Cecilia Tsang
CECILIA TSANG
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